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| 10/659,451 | 09/09/2003 | Maria Villani | 14431-16 | 4939 |

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EXAMINER

VANIK, DAVID L

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,451

Applicant(s)

VILLANI, MARIA

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's Response to Election/Restriction filed on 4/13/2005.

Election/Restrictions

Applicant's election with traverse of Claims 1-9 in the reply filed on 4/13/2005 is acknowledged. The traversal is on the ground(s) that the search of chemically and functionally distinct compositions do not present the examiner with a search burden. This is not found persuasive because claims 1-9 (class 424, subclass 401) and 10-22 (class 424, subclass 520) differ in scope as indicated by their distinct classification. Furthermore, Group I is drawn to a Porifera-derived composition, specifically from *Spongilla Lacustris*, *Spongilla fragilis* Leidy, and *Ephydatia fluviatilis*, whereas Group II is directed to a composition comprising Spongilla powder and a variety of other chemical compositions, such as coral powder, white seaweed powder and green seaweed powder. As such, claims 10-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/13/2005. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by DE4028622 ('622).

'622 disclose the preparation of a Porifera-derived product, collagen sponges (abstract). According to '622, the sponges can be processed, mixed with cosmetics or pharmaceuticals, and used in transdermal applications (Abstract). It should be noted that claims 1 and 7 are product-by-process claims. As such, claims 1 and 7 will be treated as product claims and not as method claims. By disclosing a composition comprising a Porifera-derived product, a collagen sponge material, the composition advanced by '622 et al anticipates the instant claims 1 and 7 (abstract).

The claims are therefore anticipated by DE4028622 ('622).

Claims 1-4, 7-8 are rejected under 35 U.S.C. 102(a) as being anticipated by RU 2176511 C1 ('511).

'511 disclose a dermatological composition comprising a Porifera-derived material, a fresh-water sponge of the *Spongillidae* family, and ethyl alcohol, a pharmaceutically acceptable excipient (abstract). It should be noted that claims 1 and 7 are product-by-process claims. As such, claims 1 and 7 will be treated as product claims and not as method claims. By disclosing a composition comprising a Porifera-derived product, a fresh-water sponge of the *Spongillidae* family, the composition advanced by '511 et al anticipates the instant claims 1 and 7 (abstract).

The claims are therefore anticipated by 2176511 C1 ('511).

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,821,264 ('264).

'264 disclose a gene-delivery device for applying a pharmaceutical composition to a contact surface, such as a tissue site (abstract). In one embodiment, the contact surface comprises a Porifera-derived material, a sponge material (column 10, lines 49-54). As specified by '264, the sponge material can be a natural fresh-water sponge, *Spongilla Lacustris* (column 10, line 59). The sponge material is sufficiently porous such that it can further comprise pharmaceutical compositions (column 10, lines 49 – 65). It should be noted that treating a particular kind of skin disease, such as acne, is

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considered to be a future intended use of the composition. As such, the future intended use of the instant composition is afforded no patentable weight.

It should also be noted that claims 1 and 7 are product-by-process claims. As such, claims 1 and 7 will be treated as product claims and not as method claims. By disclosing a composition comprising a Porifera-derived product, a fresh-water *Spongilla Lacustris* sponge, the composition advanced by '264 anticipates the instant claims 1 and 7 (abstract).

The claims are therefore anticipated by US patent 6,821,264 ('264).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over 2176511 C1 ('511) in view of US patent 3,896,238 ('238).

'The teachings of '511 are discussed above. '511 does not disclose a kit for packaging a skin treating composition.

'238 disclose an anti-acne composition and kit for packaging said composition (column 23, lines 2-65). Depending on the intended use, one of ordinary skill in the art would have been motivated to package a composition, such as an anti-acne composition, in a kit. Kits provide a convenient mechanism to disperse products to consumers. By combining the teachings of '238 with those of '511 and producing a kit comprising an anti-acne composition, there is a reasonable expectation that said kit would provide a convenient mechanism to disperse an anti-acne product to consumers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package an anti-acne composition, such as the one advanced in the instant application, in a kit.

Correspondence

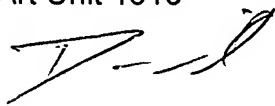
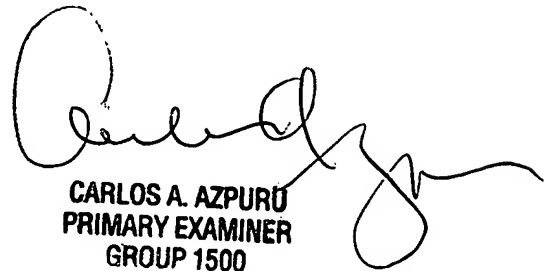
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588 . The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
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4/22/05
CARLOS A. AZPURU
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